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FDA Licensed Pfizer Vaccine Without Following Normal Approval Process, Documents Reveal

A U.S. Food and Drug Administration official authorized the release of a Biologics License Application number for Pfizer's COVID-19 vaccine while regulators were still deciding whether to approve the license, according to newly released documents.

By The Epoch Times

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By Zachary Stieber

U.S. drug regulators acknowledged deviating from the normal vaccine approval process when dealing with Pfizer's COVID-19 shot, according to newly disclosed documents.

Weeks after Pfizer and its partner BioNTech announced they started a rolling submission of documents for approval of their COVID-19 vaccine, a U.S. Food and Drug Administration (FDA) official penned a memorandum authorizing the release of a Biologics License Application (BLA) number for the shot even as regulators weighed whether to approve the BLA, one of the documents shows.

"This deviation from our normal practice is done to facilitate product labeling and distribution and is consistent with other Center practices to facilitate vaccine delivery during the declared Public Health Emergency," Christopher Joneckis, the FDA's associate director for review management, wrote in the June 17, 2021, memo.

"When providing the license number, we should communicate that this license number does not constitute any determination by FDA on the application."

Joneckis said the decision stemmed in part from the FDA having granted Emergency Use Authorization (EUA) for the shot in late 2020. That means the FDA "is familiar with and has reviewed much of the information provided in the BLA application," which primarily consisted of data used in the application for emergency clearance, he said.

EUAs can be granted if a public health emergency has been declared and the FDA determines it's "reasonable to believe" that the vaccine or other product in question "may be effective" in preventing, diagnosing, or treating the disease or condition caused by the public health threat.

BLAs require a higher threshold of evidence, demonstrating that a product is "safe, pure, and potent."

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A separate document made public this week showed that the license number was given to Pfizer even though no approval decision had been made after Pfizer requested it.

"The Applicant requested a U.S. License Number for BioNTech Manufacturing GmbH with agreement that they will not use it until after the BLA is approved," the document, a summary of a June 29, 2021, FDA meeting discussing Pfizer's application, stated.

The summary noted that Joneckis wrote the memo authorizing the release of the number "in advance of the typical notification in the approval letter." After that, the FDA "generated the license number which will be provided to the Applicant, after filing, in an email message."

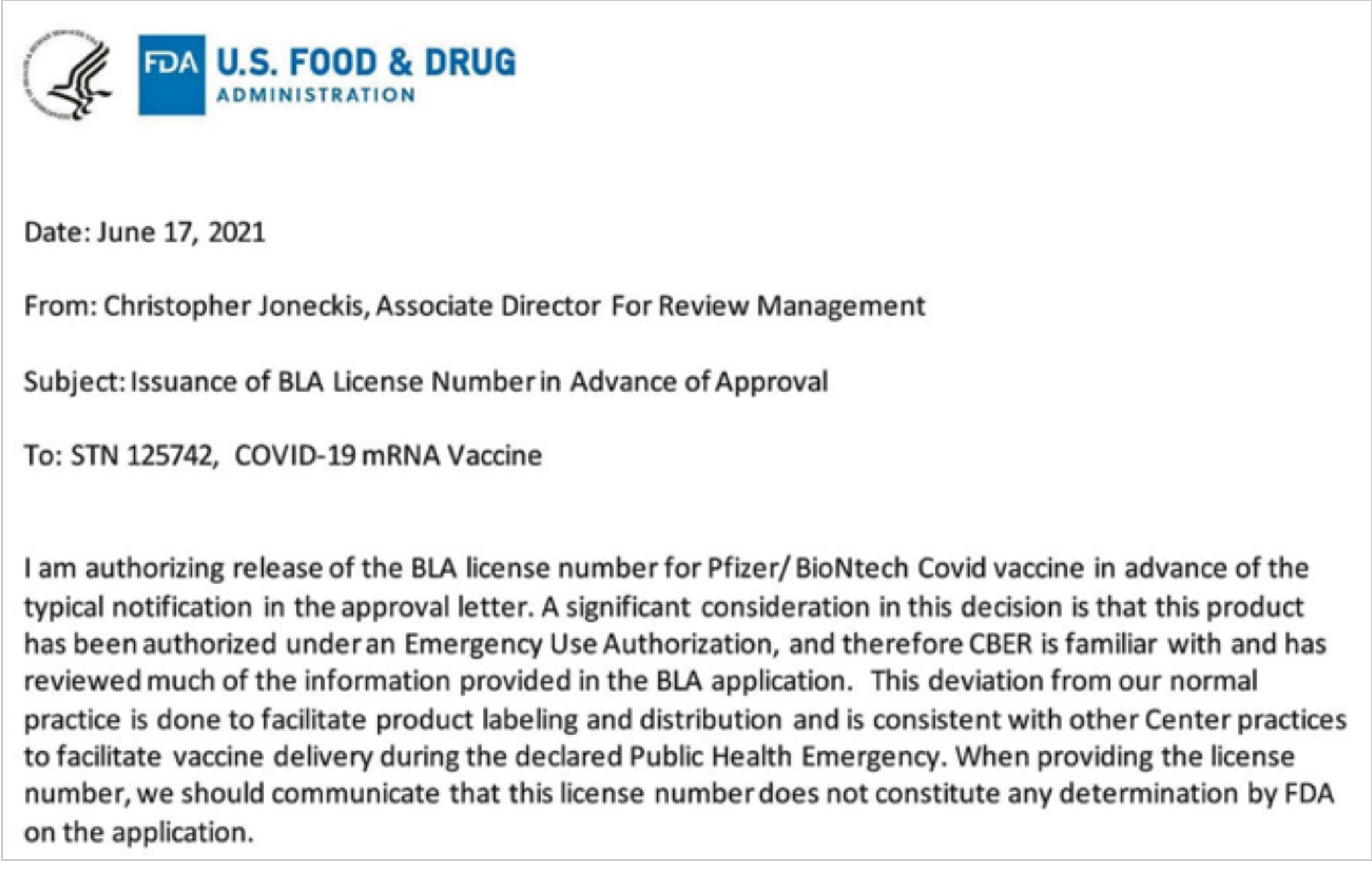
The FDA granted a BLA to Pfizer's vaccine for individuals 16 and older on Aug. 23, 2021. The vaccine was later approved for children as young as 6 months of age. The FDA has also authorized or approved multiple boosters due to the vaccine performing poorly against newer variants.

The documents were released by the Informed Consent Action Network, which successfully convinced a court to order the FDA to produce documents related to its actions on the COVID-19 vaccines after the agency had claimed it would take decades to do so.

The government has been providing Informed Consent Action Network documents in response to the suit and Freedom of Information Act requests.

Aaron Siri, a lawyer representing the network, told The Epoch Times in an email that the new documents are "another piece of evidence that supports that licensure of this product quickly became a foregone conclusion."

The FDA did not respond to a request for comment.



FDA U.S. FOOD & DRUG
ADMINISTRATION

Date: June 17, 2021

From: Christopher Joneckis, Associate Director For Review Management

Subject: Issuance of BLA License Number in Advance of Approval

To: STN 125742, COVID-19 mRNA Vaccine

I am authorizing release of the BLA license number for Pfizer/ BioNtech Covid vaccine in advance of the typical notification in the approval letter. A significant consideration in this decision is that this product has been authorized under an Emergency Use Authorization, and therefore CBER is familiar with and has reviewed much of the information provided in the BLA application. This deviation from our normal practice is done to facilitate product labeling and distribution and is consistent with other Center practices to facilitate vaccine delivery during the declared Public Health Emergency. When providing the license number, we should communicate that this license number does not constitute any determination by FDA on the application.

Advisory committee meeting 'not needed'

The FDA only held one meeting with its advisory panel, the Vaccines and Related Biological Products Advisory Committee (VRBPAC), after Pfizer and BioNTech lodged their BLA request. That meeting focused on whether to clear vaccines for younger populations, and not the new application.

During the meeting, multiple panelists expressed confusion about when they would be consulted on any BLA requests.

"Where are we at with the licensure for adults?" Dr. Archana Chatterjee, one of them, said.

"I'm still unclear when we're going to be reviewing the BLAs for [adults]," added Dr. Steven Pergram, another.

An FDA official revealed in the June 2021 internal meeting that the agency was planning on not consulting its outside advisers before deciding on Pfizer's application.

Marion Gruber, director of the FDA's Office of Vaccines Research & Review, "confirmed that, unless a significant new safety concern or other important issue is discovered during the review of the submission that would necessitate convening the VRBPAC, an Advisory Committee Meeting will not be needed for this BLA," according to the summary.

The FDA, which has never rejected an EUA or BLA request from Moderna or Pfizer related to their COVID-19 vaccines, and the Centers for Disease Control and Prevention, made a trend of bypassing the advisory panels during the pandemic, including when they authorized and recommended boosters in the fall of 2022 without any clinical data.

In another portion of the document, as justification for not calling a committee meeting, FDA officials said they had already consulted the advisory committee five times between October 2020 and June 2021 "to discuss the development, Emergency Use Authorization and licensure of COVID-19 vaccines."

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Zachary Stieber is a senior reporter for The Epoch Times based in Maryland. He covers U.S. and world news.

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Janina Buczynska
4 days ago
All irrelevant! DoD were running the whole vaccine programme under 'countermeasures' so no need for proper trials. All a performance.
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UnionMember → Janina Buczynska
2 days ago
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Virus theory is the bs to convince people to inject toxins, and the side effects get blamed on the virus lol
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